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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,582	03/31/2004	Brian Freedman	F-8266	9395

7590

09/25/2006

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EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/815,582	Applicant(s) FREEDMAN, BRIAN	
	Examiner Lezah W. Roberts	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 6-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 6-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Amendment filed July 10, 2006. All references have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness (New Rejections)

1) Claims 1 and 6-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery et al. (US 6,343,933) in view of Gaffar (WO 97/02805).

Montgomery et al. teaches compositions and methods to whiten teeth by light activation. One of the taught methods involves applying a photosensitizing containing composition to the teeth followed by an oxidizing agent composition. The compositions are then exposed to light (col. 7, lines 1-4). The photosensitizers include metal-ligands such as manganese gluconate. Especially preferred photosensitizers belong to the general class of water-soluble metal-ligand complexes, which absorb light in the range of from about 350 nm to about 700 nm. Examples of metal-coordination complexes are formed from the association of iron, manganese and copper with chelators such as ethylenediamine tetraacetic acid (EDTA). Any organic multi-dentate chelating agent capable of forming a photo-absorbing coordination complex with a metal ion can be presumed to have utility in the present inventive compositions and methods of whitening stained teeth. A number of the inventive metal-ligand complexes have an absorption

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spectrum that is pH-dependent; in general, such complexes will display a greater degree of absorption between 350 and 700 nm at a pH of greater than about 4.0, light absorption in this range increasing with increasing pH. Greater than 4 encompasses claim 6. For instance, the aqueous complex formed between 1-hydroxyethylidene-1,1-diphosphonic acid and ferrous ions is virtually transparent to visible light at pH 3.0, but absorbs strongly in the spectral region between 350 and 500 nm as the pH is raised to 7.0 (col. 7, lines 49-67 and col. 8, lines 1-26). The compositions are aqueous compositions, encompassing claim 9. Thickeners are also included in the compositions and include carboxypolymethylene polymer. A light-activated tooth whitening method, in accordance with a specific embodiment of the invention includes contacting the tooth enamel surface with the photosensitizing agent, then contacting the photosensitizer-treated tooth surface with the oxidizing compound, and, thereafter, exposing the tooth surface to light energy capable of activating the photosensitizer which, in turn, activates the oxidizing compounds at the tooth enamel surface, which encompasses what is recited in claims 10 and 13-14. It can be concluded when the tooth is exposed to light it is heated by the transfer of energy from the light to the tooth. Suitable lamps that emit actinic radiation in the preferred range of wavelengths include Xenon short arc, Mercury short arc and Mercury Xenon short arc, which encompass claim 15, Argon plasma arc, and Argon short arc lamps, among others. In regards to claims 11-12, it can be concluded the above composition are applied to dry surfaces due to the fact the teeth are exposed to the air in order to apply the compositions, thereby preventing the teeth from being moistened when the compositions are being applied to the teeth. The

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oxidizing compounds are liquid, gel, or solid compositions transparent to the wavelength(s) of light capable of activating the photosensitizing agent at the tooth surface. The oxidizing agents that may be used within the oxidizing composition include hydrogen peroxide, which is recited in the instant claims. The examples included hydrogen peroxide in the compositions at 3% and at 15%. It can be concluded the hydrogen peroxide may be present in the compositions from about 3% to about 15%, which encompasses claim 16. Therefore these values encompass claim 16. The reference discloses, within its prior art, professional compositions for whitening teeth with peroxide. The commercial product is supplied in a plastic syringe and is described in the accompanying literature as a light-activated tooth whitening gel, which contains approximately 35% hydrogen peroxide. The product is thickened to a loose, gel-like consistency with a polymer (col. 2, lines 21-29). This encompasses what is recited in claim 17 because it shows an in-office composition for tooth whitening comprising 35%. The reference differs from the instant claims insofar as it does not teach polyvinyl pyrrolidone in the compositions or a surfactant.

Gaffer et al. teach a two component whitening dentifrice compositions, which comprise a first component containing a peroxygen compound and a second dentifrice component containing a manganese coordination complex. The manganese complexes comprise of a manganese (III) and a multi-dentate ligand. The manganese coordination complexes include manganese gluconate. The two phases are combined shortly before application to the teeth wherein the manganese compound interacts with the peroxygen constituent to accelerate the breakdown and rapid release of active oxygen from the

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peroxy compound such as rapid release being effective for whitening teeth when allowed to remain on the teeth for a limited time. The amount of manganese complex activator compound present in the second component of the two phase whitening oral composition varies from a range between 0.1 to 3%, which encompasses claim 7 (page 5, lines 1-14). Other components may be added to the manganese complex composition such as surfactants and thickeners, e.g., polyvinylpyrrolidone. The vehicle may be a mixture of water and humectants and make up 40% - 80% of the dentifrice components making it an aqueous solution, which encompasses claim 9. A surfactant is used in the preparation of oral composition components to aid in the thorough dispersion of the composition throughout the oral cavity when applied thereto. Although the pH was not disclosed, a base such as sodium carbonate is also included in the compositions. The reference differs from the instant claims insofar as it does not disclose the pH of the compositions being at least 7 or the method of applying the activator solution on to the teeth before the peroxide containing solution and irradiating the teeth with light.

It would have been obvious to one of ordinary skill in the art to have used the surfactants and thickeners in the compositions of the primary reference motivated by the desire to make compositions that are thoroughly dispersed when applied to the teeth as taught by the secondary reference.

In regards to the pH of the composition being between 10.3 and 10.8, normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally

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involves the application of no more than routine skill in the art. *In re Aller* 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to have adjusted the pH of the compositions motivated by the desire to obtain optimal absorption of the taught complexes for optimal whitening of the teeth, as taught by the primary reference and supported by cited precedent.

2) Claims 1, 6-7 and 9-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery (US 6,343,933) in view of Chen (2002/0155070).

The primary reference is discussed above. The reference differs from the instant claims insofar as it does not teach incorporating polyvinyl pyrrolidone into the compositions as a thickening agent.

Chen teaches teeth whitening compositions comprising a bleaching agent and polyvinyl pyrrolidone. A basic agent, heat or light may be used to accelerate bleach results. The polyvinyl pyrrolidone as the thickening agent is preferred over carboxypolymethylene because polyvinyl pyrrolidone has the advantage of serving as a thickening agent or gelling agent while failing to: (i) interfere with release of oxygen ions from the bleaching agent or contact of those oxygen ions to the teeth to be bleached, (ii) chemically etch tooth enamel, (iii) remove calcium from tooth enamel by chelation, and (iii) solidify the dental bleach. This is due in part because it does not contain organic acid in its structure and therefore cannot acid etch or chelate teeth. It is also easily dispersed in water. Polyvinyl pyrrolidone based bleaches are enamel safe and therefore will present a significant improvement over the prior art (paragraphs 0054-0055). The

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compositions may also initially be two part compositions where the oxidizing agent is in one part and the basic substances are in the second part. The pH of the basic compositions ranges from 7 to 12 and will not include the oxidizing agent. When the pH of the oxidizing compositions is more than 7, the oxidizing agent is destabilized (paragraphs 0076-0078). The reference differs from the instant claims insofar as it does not teach the compositions comprise a magnesium gluconate and EDTA.

It would have been obvious to one of ordinary skill in the art to have used polyvinyl pyrrolidone in place of the carboxypolymethylene in the compositions of the primary reference motivated by the desire to use a thickening agent that does not interfere with release of oxygen ions from the bleaching agent or contact of those oxygen ions to the teeth to be bleached, does not chemically etch tooth enamel, does not remove calcium from tooth enamel by chelation and is easily dispersed in water, as taught by the secondary reference.

3) Claims 1 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardlik et al. (US 2002/0119174).

Gardlik et al. teach compositions, such as pharmaceutical compositions, that can be formulated into rinses, tonics, strays and ointments. The compositions may comprise manganese gluconate, polyvinyl pyrrolidone, ethylenediamine tetraacetic acid, and surfactants (see claims). Manganese gluconate may be incorporated preferably from 0.001% to 15% (paragraph 0028), encompassing claim 7. The compositions can be adjusted to the desired pH. A pH adjuster includes sodium hydroxide, a basic

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compound. The reference differs from the instant claims insofar as it does not teach the pH is greater than 7.

Normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. *In re Aller* 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to have adjusted the pH of the compositions to greater than 7 motivated by the desire to obtain optimal conditions for the taught compositions, supported by cited precedent.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Claims 1 and 6-17 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

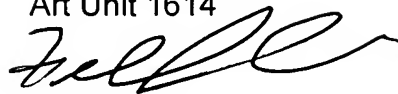
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Lezah Roberts
Patent Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read "Leah Roberts", with a long horizontal flourish extending to the right.

Frederick Krass
Primary Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read "Frederick Krass", with a long horizontal flourish extending to the right.